

1 Honorable Ronald B. Leighton
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IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

9 STORMANS, INCORPORATED, et al.,

Civil Action No. C07-5374 RBL

10 Plaintiffs,

11 vs.

12 MARY SELECKY, Secretary of the Washington
13 State Department of Health, et al.,

**PLAINTIFFS' OFFER OF PROOF
REGARDING EXPERT
TESTIMONY ON THE
MECHANISM OF ACTION OF
EMERGENCY CONTRACEPTIVES
PLAN B AND ELLA**

14 Defendants,

15 and

16 JUDITH BILLINGS, et al.,

17 Intervenors.

18 Plaintiffs hereby provide their Offer of Proof regarding expert testimony on the
19 mechanisms of action of Plan B and *ella*. By its Amended Order Regarding Motions in
20 Limine dated March 15, 2011 (Dkt #458), the Court excluded expert testimony on the
21 mechanisms of action of emergency contraceptives and in that same Order permitted the
22 parties the opportunity to submit expert reports as Offers of Proof. Attached hereto are the
23 following Offers of Proof:

**PLAINTIFFS' OFFER OF PROOF REGARDING
MECHANISM OF ACTION OF EMERGENCY
CONTRACEPTIVES (C07-5374) - 1**

ELLIS, LI & MCKINSTRY PLLC
Attorneys at Law
2025 First Avenue, Penthouse A
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206•682•0565 Fax: 206•625•1052

1. Report of Plaintiffs' expert, Elizabeth Shadigian, MD, dated November 4, 2008, regarding mechanism of action of Plan B (and related issues).
2. Report of Plaintiffs' expert, Dr. Bruce Carlson, dated October 30, 2011, regarding mechanism of action of *ella*. His curriculum vitae is also attached.

Respectfully submitted this 31st day of October, 2011.

By: /s/ Steven T. O'Ban

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**PLAINTIFFS' OFFER OF PROOF REGARDING
MECHANISM OF ACTION OF EMERGENCY
CONTRACEPTIVES (C07-5374) - 2**

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November 4, 2008

Kristen Waggoner
Ellis, Li & McKinstry
Two Union Square
601 Union Street, Suite 4900
Seattle, WA 98101-3906

RE: Stormans, Inc. et al. v. Selecky, et al.
Civil Case No. C07-5374-RBL

Dear Ms. Waggoner,

As requested, I am offering a rebuttal to the expert reports of Dr. David A. Grimes and, in part, Ms. R. Alta Charo in the case, *Stormans, Inc. et al. v. Selecky et al.*, after reviewing the information you have previously sent to me.

Qualifications

I graduated from Purdue University in West Lafayette, Indiana, in 1985 with a B.S. in Chemistry, and I received an M.D. from Johns Hopkins University School of Medicine in Baltimore, Maryland, in 1990. I have been board certified in Obstetrics and Gynecology since 1996 and am licensed to practice medicine in the State of Michigan. I am a Fellow of the American College of Obstetricians and Gynecologists (ACOG).

I am also Adjunct Clinical Associate Professor of Obstetrics and Gynecology at the University of Michigan Medical Center in Ann Arbor, Michigan. I have previously been full time faculty from 1994-2006 at the University of Michigan as Clinical Assistant Professor (1994-2002) and then as Clinical Associate Professor (2002-2006), where I had a full-time clinical obstetrics and gynecology practice, as well as teaching and research duties. I currently have a clinical private practice in Gynecology and WomanCare, WomanSafeHealth, where I specialize in caring for women with a history of trauma, including their physical and psychological needs. I treat women with post-traumatic stress disorder, depression, anxiety, etc., as well as offer consultative gynecology and primary care clinical services to women and girls, including those pregnant. I also employ and work with a clinical psychologist as a part of the care my office provides to women in need.

At WomanSafeHealth, we welcome women and girls of every age and ability, size, shape, color and sexuality, from all social, spiritual and cultural backgrounds. We provide a safe, family-friendly environment in which a woman can seek, explore, define and receive Gynecology and WomanCare health services. WomanCare meets a woman's physical and psychological health needs through conventional and alternative approaches, and encourages and promotes self-care. We welcome all women, including those who feel unwelcome in other medical settings and those who have experienced physical and/or sexual violence or disrespect.

For over 20 years I have counseled and treated hundreds of women who have been at risk for unintended pregnancy, including, but not limited to, sexual assault victims, some of whom have chosen to take emergency contraception (EC) and some who have declined EC. I also care for women who have had abortion complications and perform research in this area.

My other areas of teaching and research include violence against women, including domestic violence; sexual assault; child abuse; elder abuse; and child sexual assault. I have published in the areas of abortion complications, violence against women, and have co-authored the University of Michigan depression clinical care guidelines. I am a journal reviewer for several national journals and have received on three occasions the American Medical Women's Association "Gender Equity Award" for promoting a gender-fair environment for the education and training of physicians at the University of Michigan Medical School. My Curriculum Vitae, which sets forth in more detail my background and qualifications, is attached.

Community Service

I am currently Matriarch, Chairwoman of the Board of Directors and co-Founder of the Battered Women and Children's Memorial Garden, a 501(c)3 nonprofit organization in Ann Arbor, Michigan. Its mission is:

"The Battered Women and Children's Memorial Garden is an alliance of people desiring an end to violence. We form a beacon of hope to honor the disempowered, remember those lost and inspire justice through bearing witness, education, advocacy and service."

Its guiding principles are: remain loyal to the disempowered; lead the discussion; ask questions; challenge gendered assumptions; expose and oppose oppression; apply accountability; honor diversity; practice responsible environmental stewardship; speak truth to power; make privilege visible; and eradicate misogyny.

I am a regular speaker at local women's groups and community events primarily focusing on women's empowerment and prevention of violence against women.

Publications Authored in the Preceding Fourteen Years

The publications I have authored in the preceding fourteen years are set out in Curriculum Vitae, which is attached.

Compensation to be Paid

My consultation fee is \$350 per hour. Time spent testifying or preparing for either trial or deposition is \$400 per hour. My understanding is that all travel-related expenses will also be paid, as well as any out-of-pocket expenses.

Expert Testimony Given at Trial or Deposition in the Preceding Six Years

The expert testimony I have given in the past six years is set out in my Curriculum Vitae, which is attached.

REBUTTAL

1. General rebuttal

Scientifically, it is undisputed that human life begins at fertilization. Barr Pharmaceutical's own packet insert warns that Plan B may prevent implantation of the fertilized egg (embryo) into the uterus. Therefore, any regulation that requires plaintiffs to dispense Plan B requires them to participate in the potential termination of a human life regardless of how one chooses to define "pregnancy" at any particular time. Providers, such as plaintiffs, who object to dispensing Plan B, do so with the belief that they are treating two human beings: the woman and the embryo. Such providers should not be forced to participate in the death of the embryo, which is unquestionably human life.

2. Rebuttal to Dr. David A. Grimes

A. Definitions

Dr. Grimes in his expert report sidesteps whether the fertilized egg is a human life. He instead labors to focus on a definition of pregnancy as the implantation of the embryo into a woman's uterus or the Fallopian tube, cervix, ovary, or abdomen (ectopic pregnancy). Dr. Grimes relies on a non-scientific and artificial definition of pregnancy, which has been conveniently redefined by certain professional organizations over the years. Dr. Grimes' perpetuation of this definition has the unfortunate effect, intended or not, to mislead women and society into believing that they are not terminating a human life if the embryo is not allowed to undergo implantation.

Promoting the misconception that pregnancy begins at implantation furthers the erroneous concept that abortion cannot occur prior to implantation. Dr. Grimes confuses the issue by purporting that Plan B is a "contraceptive" when it prevents the implantation of an embryo, rather than, accurately, an abortifacient. He states that, "Many patients and some professionals (both clinicians and pharmacists) confuse emergency contraception with medical abortion, since both are used or occur after intercourse." Those who believe life begins with fertilization and object to Plan B, such as plaintiffs, understand the difference between emergency contraception and medical abortion. Both may destroy human life after fertilization.

Other examples of Dr. Grimes' crafting of language include the use of the non-scientific term "pre-embryo" instead of either "zygote" for the single-cell stage, or "embryo" or "pre-implantation embryo," which are the historical, standard terms for the human being prior to implantation. While some medical dictionaries and textbooks have shifted the definitions of the aforementioned words to obfuscate when life begins for other interests, a review of earlier dictionaries and textbooks demonstrates the standard embryological and obstetrical understanding of the development of a human being as beginning with fertilization. For example, the first page of Moore's human embryology textbook explains, "Human development is a continuous process that begins when an ovum from a female is fertilized by a sperm from a male. Growth and differentiation transform the zygote, a single cell formed by the union of the ovum and the sperm into a multi-cellular adult human being." Regardless of when Dr. Grimes chooses to characterize a woman as "officially" pregnant, a fertilized egg in a woman's body means that human life has begun to grow within her and, in most cases, that life will develop into an independent, fully-formed human being.

B. Mechanisms of action of Plan B

Dr. Grimes also references Plan B's mechanisms of action. I agree with Dr. Grimes when he states "the potential mechanism(s) of action have not been thoroughly studied and hence are not completely understood." However, some data do exist. The mechanisms of action can be broadly divided into two categories, especially for those people concerned with the issue of when human life begins – pre-fertilization and post-fertilization. Pre-fertilization effects of hormonal contraception include, but are not limited to:

- a) prevention or delay of ovulation, by possibly inhibiting the release of an egg;
- b) cervical mucus changes that do not allow sperm to function properly;
- c) alterations in the transport of sperm or egg through the reproductive tract;
- d) interference with corpus luteum function; and
- e) direct interference with fertilization.

Possible post-fertilization effects of hormonal contraception include, but are not limited to:

- a) alterations in the transport of the zygote or embryo through the reproductive tract;
- b) interference of corpus luteum function; and
- c) prevention of embryo implantation into the uterus through altering the receptiveness of the endometrium and inhibiting implantation of a fertilized egg.

The ACOG Practice Bulletin "Emergency Contraception" Number 69, December, 2005 cites at least five studies documenting histologic and biochemical changes in the endometrium which may inhibit implantation of a fertilized egg, and then goes on to say that other studies refute those.

Dr. Chris Kahlenborn and his colleagues have asserted that emergency contraception taken in the pre-ovulatory, ovulatory or post-ovulatory phases of the menstrual cycle may have a post-fertilization effect on the endometrium, thus reducing the probability of implantation, based on the studies they reviewed.

Barr Pharmaceuticals in their package insert finds it necessary to warn women that Plan B may prevent implantation of the fertilized egg into the uterus. The United States Food and Drug Administration similarly describes Plan B's mechanism of action. Dr. Grimes' suggestion that there is no scientific evidence to support the fact that Plan B may prevent implantation is inaccurate.

C. Safety and Plan B

Although not relevant to the discussion of when human life begins or Plaintiff's religious objections, Dr. Grimes makes several other inaccurate statements – about the safety of Plan B and about unintended pregnancy (see section D). He purports that Plan B is safe. He says that "No woman anywhere in the world has ever been documented to have been seriously injured or killed by emergency contraception." On the contrary, it appears that the ectopic pregnancy rate following Plan B use can be as high as 6%. In 2003, the United Kingdom's Department of Health alerted British physicians to this possible complication based on post-marketing surveillance in which 201 EC failures were found to contain twelve ectopic pregnancies – or a 6% rate – triple the expected rate for the UK

D. Unintended Pregnancy

Contrary to Dr. Grimes' report, "unintended" pregnancy does not threaten women's health any more than intended pregnancy or just pregnancy in general. He does not cite one source to substantiate the claim that, if a pregnancy is intended, this changes any health risk associated with that pregnancy. It is rare for pregnancy to threaten a woman's life.

In several systematic reviews, data on effects of increased access to emergency contraceptive pills on pregnancy rates and use of the pills concluded that "increased access to emergency contraceptive pills enhances use but has not been shown to reduce unintended pregnancy rates." Further, several recent studies, some of which were in the systematic review, have shown that advanced provision of emergency contraception does not decrease unintended pregnancy rates or abortion rates.

In sum, Dr. Grimes fails to properly acknowledge when human life begins and provides an incomplete (and misleading) analysis of Plan B's method of action, safety and effect.

3. Rebuttal of Ms. Charo, in part

I wish to make one point with regard to Ms. Charo's analysis. Health-care providers that acknowledge the scientific fact that a human being is created at the time of fertilization inherently have two patients that are being cared for -- the woman and the baby. Therefore, Ms. Charo's assumption that pharmacists who refuse to dispense emergency contraception are acting out of personal interests, gain or satisfaction is not valid. Objecting pharmacists believe they have two patients that they are advocating for and that both deserve life. While it may be simpler to focus only on the woman, such a singular focus disregards the fact that Plan B can terminate human life.

Sincerely,



Elizabeth Shadigan, MD

Data or Information Considered in Forming Opinions

Actual Use Study, Volumes 27-30 of sNDA 21-045, Phase 3 Non-Comparative Case Series Study of Plan B Levonorgestrel Emergency Contraceptive Pills Provided Using a Simulated Over-the-Counter Approach; Women's Capital Corporation (The sponsorship was transferred to the Barr Research in Nov., 03) Investigators: Family Health International (FHI), Research Triangle Park, NC, January, 2003.

American College of Obstetricians and Gynecologists. Practice Bulletin: Clinical Management Guidelines for Obstetrician-Gynecologists. (Replaces Practice Bulletin Number 25, March 2001) Number 69. December, 2005. Washington, DC.

Annual Estimates of the Population by Sex, Race, and Hispanic Origin for Washington: April 1, 2000 to July 1, 2007. Available from: <http://www.census.gov/popest/states/asrh/SC-EST2007-03.html>.

Barr Pharmaceuticals. Plan B, Levonorgestral Package Insert, 2008.

Berliner L, Fine D, Moore D. Sexual Assault Experiences and Perceptions of Community Response to Sexual Assault: A Survey of Washington State Women. Office of Crime Victims Advocacy, Washington State Office of Community Development, October, 2001.

Condic, M. When Does Human Life begin? A Scientific Perspective. 2008. Thronwood, NY: The Westchester Institute.

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Hu X, Cheng L, Hua X, Glasier A. Advanced Provision of Emergency Contraception to Postnatal Women in China Makes No Difference in Abortion Rates: A Randomized Controlled Trial. *Contraception*. 2005;72:111-16.

Kahlenborn C, Stanford JB, Larimore WL. Postfertilization Effect of Hormonal Emergency Contraception. *Annals of Pharmacotherapy* 2002; 465-470.

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Polis C, Schaffer K, Blanchard K, Glasier A, Harper C, Grimes D. Advance Provision of Emergency Contraception for Pregnancy Prevention (full review). Cochrane Database Systematic Review 2007 April; 2: CD005497. DOI: 10.1002/14651858.pub2. Available from: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=17443596&dopt=Citation.

Raine T, Harper C, et al. Direct Access to Emergency Contraception Through Pharmacies and Effect on Unintended Pregnancy and STI's : A Randomized Controlled Trial. JAMAQ 2005; 293: 54-62..

Raymond EG, Trussell J, Polis, CB. Population Effect of Increased Access to Emergency Contraceptive Pills. *Obstetrics & Gynecology* 2007;109:181-188, available from <http://www.greenjournal.org/cgi/content/abstract/109/181-188>.

Reece EA, Hobbins JC, Mahoney MJ, Petrie RH. Medicine of the Fetus & Mother. Philadelphia, PA: J.B. Lippincott Company, 1992.

Bruce M. Carlson
1345 Waterford Drive
Golden Valley, Minnesota 55422

October 30, 2011

Mr. Steven O'Ban
ELLIS, LI & MCKINSTRY PLLC
2025 First Avenue, Penthouse A
Seattle, Washington 98121-3125

Dear Mr. O'Ban:

I am responding to your request for an opinion on both the science and the interpretation of that science with respect to the possibility that under some circumstances the drug Ella may have a direct or indirect detrimental effect on the viability of an early human embryo within the reproductive tract of the mother. Specifically, you requested an update on developments since the report of Dr. Elizabeth Shadigan, which was submitted on November 4, 2008 and which covered only Plan B, since Ella had not as of that time been approved by the FDA.

Qualifications

My name is Bruce M. Carlson, M.D., Ph.D., and my present position is Professor Emeritus at the University of Michigan Medical School. From 1966-2000, I was a faculty member in the Department of Anatomy and Cell Biology at the University of Michigan and served as Chairman of that Department from 1988-2000. From 2000-2004, I was Director of the Institute of Gerontology and retired as a full-time faculty member of the University in 2006. I have also served as President of the American Association of Anatomists and President of the Association of Anatomy, Cell Biology and Neurobiology Chairpersons.

My curriculum vitae is presented as Exhibit 1. I have taught human embryology at the University of Michigan Medical School for the past 42 years and

among my 12 single-authored books are two widely used textbooks of embryology - Patten's Foundations of Embryology, 3rd - 6th editions and Human Embryology and Developmental Biology, 1st - 4th editions. The fifth edition of this text is in preparation. I have conducted and have published the results of laboratory research on vertebrate embryos and have had extensive research contact with the Patten Human Embryo Collection at the University of Michigan and the human embryo collections residing in the National Museum of Medicine in Washington, DC, as well as human embryology collections at Charles University in Prague, Czechoslovakia.

Report

Ella (ulipristal acetate [UPA], or CDB-2914 or VA2914 in laboratory parlance) is a compound that competes with natural progesterone by selectively binding to the normal progesterone receptors within the female reproductive tract. Ulipristal blocks the effect of progesterone. The paragraphs below summarize recent research and interpretation regarding post-fertilization effects of this compound.

Since Ella was approved for emergency contraceptive use by the FDA in August, 2010, there has been a spate of new research reports and published comments. Ulipristal does interfere with cellular and molecular events in the pregestational uterus in a manner that could affect the ability of the early embryo to adhere to and/or implant into the endometrial lining of the uterus. According to the literature, a toxic effect on the embryo itself cannot be excluded. Below I list direct quotations from representative scientific and medical publications that are relevant to the generalizations given above.

- 1) From Stratton et al. (2010). "The current study was the first dose-ranging study to document significant endometrial effects with low doses of CDB-2914 given in the early luteal phase."(p. 2039). These authors found decreased endometrial thickness,

inhibition of endometrial development and decreased expression of L-selectin ligands, each of which is important in the implantation process.

- 2) From Bouchard et al. (2011). "Studies in baboons and humans have demonstrated that single doses of CDB 2914 or ZK 137-316 also alter endometrial development." (p. 1178). Altered endometrial development is potentially inimical to the implantation of the embryo or to its well-being after implantation.
- 3) From Glasier et al. (2010). "Although an endometrial effect, and therefore an additional postovulatory mechanism of action, cannot be excluded, the dose of ulipristal acetate used in this trial was specifically titrated for emergency contraception on the basis of inhibition of ovulation and might be too low to inhibit implantation." (p. 560). This much cited study was a clinical, not a laboratory study, and the data obtained do not allow definitive statements to be made about the mechanism of action of the drug post-fertilization.
- 4) From Kim et al. (2011). "Ulipristal exerts its pharmacological activity by binding to the body's progesterone receptors to produce an anti-progesterone contraceptive effect on the ovary (by suppressing or delaying ovulation) and on the endometrium (by decreasing endometrial thickness)." (p. 2 of 9 – electronic version). Decreasing endometrial thickness is considered to represent a condition not conducive to the process of implantation or maintenance of the embryo.
- 5) From Gemzell-Danielsson and Meng (2010). "Treatment with UPA resulted in a significant dose-dependent decrease in endometrial thickness as well as an increase in glandular P receptors." (p. 56). This sentence documents, without presenting the implications, that ulipristal causes effects on the female reproductive tract that could affect implantation of the embryo.
- 6) From Gemzell-Danielsson and Cameron (2011). "The effect of UPA on the endometrium has been demonstrated to be dose-dependent." ..."This might suggest

that the EC dose of UPA may not exert antifertility effects on the endometrium." (p. 468). This statement is in reference to the study of Glasier et al. (2010). (See comment in last sentence of #3 above.) The significance of this comment is diminished because the authors appear to be relying principally on the Glasier et al (2010) study. As noted in reference #3 above, that study does not allow definitive statements to be made about the mechanism of action of the drug post-fertilization.

- 7) From Keenan (2011). In referring to his previous paragraph, "The ultimate reason for this failure to carefully elucidate the ulipristal acetate mechanism(s) of action is uncertain. This type of study had not been done for other FDA-approved methods of EC [emergency contraception]. However, it is clear that a postfertilization mechanism of action would be objectionable to many patients and health-care professionals who might use ulipristal acetate." (p. 814). In this article and in this quotation, Dr. Keenan comments on the lack of testing that would determine whether or not ulipristal might have an effect on post-fertilization development.
- 8) From Snow et al. (2011). "As ulipristal acetate demonstrates structural similarity to mifepristone, which when administered in a single dose terminates pregnancy, much debate regarding the potential mechanism of action of ulipristal acetate continues to occur among various parties, primarily on the basis of ethical and religious concerns. This controversy also stems from the fact that the primary mechanism of action of ulipristal acetate has not been clearly defined, as well as the fact that pregnancy must be excluded prior to its administration. As a result of these factors, certain groups could make the argument that ulipristal acetate could be used to terminate pregnancy." (p. 785). Coming from a group of authors involved in regulatory affairs, this article and the above quote reflect the uncertainty about the postfertilization effects of this drug.
- 9) From CHMP Assessment Report for Ellaone (EMEA) (2009) "In conclusion, the mechanism of action, as claimed in 5.1 of the SPC "*The primary mechanism of action*

is thought to be inhibition or delay of ovulation, but alterations to the endometrium may also contribute to the efficacy of the product", is sufficiently documented. " This report, from a European regulatory agency, represents an objective opinion concerning the biological and pharmacological properties and effects of the drug in question.

In conclusion, in my professional opinion, both the scientific data and the opinions of scientists and medical practitioners strongly suggest that there are sufficient grounds for a pharmacist and/or a pharmacy owner to conclude that under some circumstances the use of Ella could interfere with the life and further development of a human embryo.

Sincerely yours,



Bruce M. Carlson, M.D., Ph.D.
Professor Emeritus
University of Michigan

Literature Cited

Bouchard P et al. (2011) Selective progesterone receptor modulators in reproductive medicine: pharmacology, clinical efficacy and safety. *Fertil. Steril.*, 96:1175-1189.

EMEA(European Medicines Agency) 2009 CHMP Assessment Report for Ellaone. Procedure No. EMEA/H/C/00127. Doc. Ref: EMEA/261787/2009, 49 pp.

Gemzell-Danielsson K, Cameron ST (2011) Ulipristal acetate (ellaOne) for emergency contraception: review of the clinical evidence. *Clin. Investig.*, 1:467-472.

Gemzell-Danielsson K, Meng C-X (2010) Emergency contraception: potential role of ulipristal acetate. *Internat. J. Women's Health*, 2:53-61.

Glasier AF et al. (2010) Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. *The Lancet*, 375:555-562.

Keenan JA (2011) Ulipristal acetate: Contraceptive or contragestive? *Ann. Pharmacotherapy*, 45:813-815.

Kim A et al. (2011) Ulipristal acetate ella): A selective progesterone receptor modulator for emergency contraception. *Pharmacy & Therapeutics*, 36:325-326, 329-331.

Snow SE et al. (2011) Ulipristal acetate for emergency contraception. *Ann. Pharmacotherapy*, 45:780-786.

Stratton P et al. (2010) Endometrial effects of a single early luteal dose of the selective progesterone receptor modulator CDB-2914. *Fertil. Steril.*, 93:2035-2041.

CURRICULUM VITAE

Name: Bruce M. Carlson

Education:

1951-1955 St. Louis Park High School, St. Louis Park, Minn.,
1955-1959 B.A., Summa cum laude Gustavus Adolphus College, St. Peter, Minn. (Majors: Biology, Languages and Chemistry)
1959-1960 M.S., Cornell University, Ithaca, New York (Major: Ichthyology; Minor: Embryology and Histology)
1960-1965 M.D., Ph.D., University of Minnesota, Minneapolis (Major: Anatomy; Minor: Zoology)

Graduate and Research Fellowships:

NSF Graduate Fellowship 1959-1960
New York State Museum and Science Service Research Honorarium 1960
USPHS Graduate Fellowship 1962-1965
U.S. National Academy of Sciences Exchange with the USSR (Institute of Developmental Biology, Moscow) 1965-1966, 1978
U.S. National Academy of Sciences Exchange with Czechoslovakia (Institute of Physiology, Prague) May-Sept., 1971
U.S. National Academy of Sciences Exchange with Czechoslovakia (Institute of Physiology, Prague) Sept.-Oct. 1972
Fulbright Fellow, Hubrecht Laboratory, Utrecht, Netherlands 1973-74
U.S. National Academy of Sciences Exchange with Czechoslovakia (Institute of Physiology, Prague) June 1974, May 1975, Sept. 1976, Nov. 1977, Sept. 1978, Oct. 1979, Nov. 1980
Josiah Macy, Jr. Fellowship to University of Helsinki, 1981-1982
Fogarty Senior International Fellowship, NIH to University of Otago, New Zealand, 1999-2000

Academic Appointments:

Assistant Professor of Anatomy, University of Michigan, 1966-1970
Associate Professor, 1970-1975
Professor of Anatomy, 1975-
Professor of Biology, 1979-
Chairman of Anatomy and Cell Biology 1988-2000
Research Scientist, Institute of Gerontology 1989-
Director, Institute of Gerontology 2000-2004

Teaching Experience:

Microscopic Anatomy
Medical Embryology
Developmental Anatomy (Graduate)
Embryology (Inteflex)
Regeneration in Vertebrates
Developmental Biology
Analysis of Development
Elementary Anatomy
Numerous research courses and seminars

Consulting Positions: Fetzer Institute, Kalamazoo

Fellow 1992-96
Trustee 1997-
Expert Witness 2000-

Scientific Activities at National, State or Civic Levels:

Co-editor - Monographs in Developmental Biology, S. Karger & Sons
Co-editor - American Journal of Anatomy
Co-editor - Experimental Cell Biology
Co-editor - Ontogenesis
Co-editor - Cell Transplantation
Anatomy Editor - Encyclopedia Americana
Editorial Board – Basic and Applied Myology
Study Commission on Man, Medicine and Theology - Lutheran Church in America, 1969-1972, 1979-1981
Life Sciences Review Panel - Fulbright-Hayes Program, 1976-1979. Chairman, 1979
Advisory Committee on USSR & Eastern Europe - U.S. National Academy of Sciences, 1977-1981
American Association of Anatomists, Morphogenesis Club - organizing committee, 1976-1978
Misc. symposium planning committees
V.A. Advisory Committee on Regeneration Research, 1982-, Chairman, 1990
NASA consultant on developmental biology in space, 1984-1985
N.A.S.-N.R.C. Committee on developmental biology in space, 1984-1985
Association of Anatomy Chairmen, Executive Committee, 1990-1992
Association of Anatomy, Cell Biology & Neurobiology Chairpersons, President, 1995
American Association of Anatomists
Executive Committee, 1993-1997
President 1997-1999
Finance Committee, 1999-2001
Membership Committee, 1999—2001
Awards Committee, 1999-2001
Nominating Committee, 2002
American Society of Zoologists, 1966-1990, Chairman of Developmental Biology Division, 1986
National Board of Medical Examiners, 1994-1996
FASEB Summer Research Conferences Board, 1995-1998
Biomedical Caucus, 1994-1995
Anatomical Record Task Force, Chair, 1997-1998

FASEB Publications Committee 1999-2001
European Union Muscle Aging Research Group, 2000-2003
International Embryological Terminology Committee (FIPAT) 2011-

Grant reviewing:

NIH - Misc. Study Sections, ad hoc
NSF
National Foundation - March of Dimes
Medical Research Council of Australia
Veterans Administration
NASA
Hong Kong Research Council
MRC - England
Czech Academy of Sciences
Medical Research Council of New Zealand
Medical Research Council of Ireland
Academy of Sciences of Georgia

Honors and Awards:

Sigma Xi, Iota Delta Gamma
First Decade Award for "early achievement", Gustavus Adolphus College, 1969
AAAS Newcomb-Cleveland Prize for 1972
Distinguished Alumni Award, Gustavus Adolphus College, 1978
Fellow, American Association for the Advancement of Science, 1994
Elizabeth Crosby Award for Basic Science Teaching, University of Michigan, 1995
Kaiser-Permanente Teaching Award, University of Michigan, 1997
Listed in Who's Who in America, 1997
Russian Academy of Natural Sciences, 1998
Memorial Medal for 650th Anniversary, Charles University, Prague, 1999
OVPR Recognition Award, University of Michigan, 2003
Henry Gray Award, American Association of Anatomists, 2004
Silver Medal in Biomedical Research, Russian Academy of Natural Sciences, 2004

Society Memberships:

American Association for the Advancement of Science
Sigma Xi
American Society of Zoologists
American Association of Clinical Anatomists
American Association of Anatomists
New York Academy of Sciences
American Society of Ichthyologists and Herpetologists
Society for Developmental Biology
International Society of Developmental Biology
FASEB
Gerontological Society of America

Ph.D. Students:

Mikel H. Snow, Ph.D. - 1971
Linda Hsu, Ph.D. - 1971
Gene L. Trupin, Ph.D. - 1973
Harry G. Goshgarian, Ph.D. - 1975
Franz S.F. Mong, Ph.D. - 1975
Patrick W. Tank, Ph.D. - 1976

Sherry L. Rogers, Ph.D. - 1981
Mark D. Womble, Ph.D. - 1983
Rachel Must, Ph.D. - 1983
Frederick J. Carey, Ph.D. - 1985
Peter Loubert, Ph.D. - 1986
Kate Stocker, Ph.D. - 1987
Gregg Phillips, Ph.D. - 1987
Lynn Billington, Ph.D. - 1995
Robert Phillips, Ph.D. - 1995
Hema Rengen

Postdoctoral Fellows and Visiting Scholars:

Susan D. Hill - 1969
Shahzad H. Mufti - 1974-75, 1980-81
Fay M. Hansen-Smith - 1975-77
David M. Bader - 1978-80
Mary R. Coan - 1978-81
Victor I. Mitashov - 1981, 1987
Danyun Lu - 1983-84
Steinar Okland - 1986-1987
Milos Grim - 1987
Yves Thouveny - 1988
Christine Viguie - 1991-1994
Da-Xing Lu - 1992-93
Andrei Borisov - 1994-
Mohammad Jamali - 1994-1996
Huang Shi-Kai - 1994-1995
Joseph Nnodim - 1996-2000
Eduard Dedkov - 1996-
Tatiana Kostrominova-1998-
Ameed Raoof - 1998

Committee and Administrative Services:

Anatomy Department:

Committee on Graduate Instruction - Chairman
Animal Care Committee - Chairman
Seminar Committee - Chairman
Graduate Board

Graduate Review and Promotions Committee - Chairman
Research Committee - Chairman
Recruitment Committee
Promotions Committee
Executive Committee
Space Committee
Internal Review Committee - Chairman
Medical Library consultant
Baker Memorial Lecture Committee - Chairman

Division of Biological Sciences:

Graduate Admissions Committee
Awards Committee
Curriculum Committee
Executive Committee

Medical School:

Faculty Conference on Curriculum
Ad Hoc Committee to Develop Medical Scientist Training Program
Review Committee for Behavioral and Neurosciences Course-Co-chairman
Review Committee for Psychiatry Department
Miscellaneous Inteflex committees
Operating Committee, Medical Scientist Training Program
External Review Committee for Anatomy and Cell Biology Department
Faculty Grievance Panel
Search Committee for Anatomy Chairman
Executive Committee
Academic Program Advisory Committee
Steering Committee and Advisory Committee - Program on Organogenesis
Library Committee

Institute of Gerontology

Director
Executive Committee
Seminar Committee
Shock Center Steering Committee
External Advisory Committee

University:

Ad Hoc Committee on a University Program for Students in the Biomedical Sciences
Divisional Board - Graduate School
Supervising Committee - Program on Medical and Biological Illustration
Miscellaneous search and review committees related to Center for Human Growth and Development
Dental Research Institute - Scientific Advisory Committee
Neurosciences Review Committee
Theatre Department Review Committee
Developmental Biology Training Program-Director
International Studies Advisory Council

Research Computing Policy Committee
Research Computing Advisory Committee
Nathan Shock Center of Excellence Steering Committee
Rodent Research Resources Committee

Community Services:

Ann Arbor Symphony - 1967-1973
Trinity Lutheran Church - Vestry, 1973-1980; Adult Education Committee, Chairman, 1976-1980; Council, 1992-1996; Endowment Board, 1999-2004
Peace Neighborhood Center - Property Committee, 1976-1981
Loch Alpine Lakes Committee, 1993-2003
Loch Alpine Board, 1997-2000
Environment and Ecology Committee, Ten Mile Lake Association, Co-Chair 2005-
Ten Mile Lake Association, President, 2009-2011
Union Congregational Church, Personnel Committee, 2010-

Research Support

Carlson, B.M., P.I. NIH PO1 AG10821-6-10 Muscle Denervation and Regeneration: Influence of Aging. Project Director. 01/01/98-6/30/03. TC \$5,013,279.

Faulkner, J.A., P.I. NIH P30 AG13283 Nathan Shock Center of Excellence, Biology of Aging.
Morphology Core Director. DC: \$54,301 for -07 year.
Research and Development Core Director. DC. \$109,824 for -07 year

Carlson, B.M., P.I. Improving Muscle Power and Mobility of Elderly Men and Women.
Michigan Life Sciences Corridor, 09/15/02 – 09/14/05. TDC: \$3,838,082.

Publications

Completed Publications in Scientific Journals:

1961 Carlson, B.M. A chromatographic analysis of the bound amino acids in lamprey muscle. *J. Exp. Zool.*, 147: 43-56.

1962 Glass, A.W., W.J. Scidmore and B.M. Carlson. A probe technique for sexing some freshwater fishes. *Investigational Report No. 250*, Minn. Conservation Dept., 10pp.

1966 Carlson, B.M. Inhibition of limb regeneration in adult *Triturus viridescens* treated with actinomycin D (in Russian). *Doklady Akad. Nauk SSSP*, 171:229-233.

1967 The histology of inhibition of limb regeneration in the newt, *Triturus*, by actinomycin D. *J. Morph.*, 122:249-263.

1967 Carlson, B.M. Studies on the mechanism of implant-induced supernumerary limb formation in urodeles. I. The histology of supernumerary limb formation in the adult newt. *J. Exp. Zool.*, 164:227-242.

1967 Carlson, B.M. and C.F. Morgan. Studies on the mechanism of implant-induced supernumerary limb formation in urodeles. The effect of heat treatment, lyophilization and homogenation on the inductive effects of frog kidney. *J. Exp. Zool.*, 164:243-249.

1967 Faustov, V.S. and B.M. Carlson. Changes in the levels of ATP and respiration in regenerating axolotl extremities (in Russian). *Doklady Akad. Nauk. SSSR*, 176:728-730.

1968 Carlson, B.M. Regeneration of the completely excised gastrocnemius muscle in the frog and rat from minced muscle fragments. *J. Morph.*, 125:447-472.

1968 Carlson, B.M. Ontogenetic development and anatomical distribution of a supernumerary limb-inducing factor. *Experientia*, 24:1064-1066.

1968 Carlson, B.M. Regeneration research in the Soviet Union. *Anat. Rec.*, 160:655-674.

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1970 Carlson, B.M. The effect of x-irradiation and beryllium nitrate upon implant-induced supernumerary limb formation in the newt. *Oncology*, 24:31-47.

1970 Carlson, B.M. The regeneration of a limb muscle in the axolotl from minced fragments. *Anat. Rec.*, 166:423-436.

1970 Carlson, B.M. Regeneration of the rat gastrocnemius muscle from sibling and non-sibling fragments. *Am. J. Anat.*, 128:21-32.

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1971 Carlson, B.M. The distribution of supernumerary limb-inducing capacity in tissues of Rana pipiens. *Oncology*, 25:365-371.

1972 Carlson, B.M. Muscle morphogenesis in Urodele limb regenerates following removal of the stump musculature. *Devel. Biol.*, 28:487-497.

1972 Carlson, B.M. and E. Gutmann. Development of contractile properties of minced muscle regenerates in rats. *Exp. Neurol.*, 36:239-249.

1973 Carlson, B.M. The regeneration of skeletal muscle - a review. *Am. J. Anat.*, 137:119-150.

1973 Vyskocil, F., B. Carlson and E. Gutmann. Changes in resting membrane potential and contractility of innervated and denervated skeletal muscle free grafts in the rat. *Pflügers Arch.*, 344:181-186.

1974 Carlson, B.M. Regeneration from short stumps of the rat gastrocnemius muscle. *Experientia*, 30:275-276.

1974 Carlson, B.M., S.E. Civiletto and H.G. Goshgarian. Nerve interactions and regenerative processes occurring in newt limbs fused end-to-end. *Devel. Biol.*, 37:248-262.

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1974 Carlson, B.M. and E. Gutmann. Transplantation and "cross-transplantation" of free muscle grafts in the rat. *Experientia*, 30, 1292-1294.

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1975 Richards, C.M., B.M. Carlson and S.L. Rogers. Regeneration of digits and forelimbs in the Kenyan reed frog Hyperolius viridiflavus ferniquei. *J. Morphol.*, 146:431-445.

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1976 Carlson, B.M. A quantitative study of muscle fiber survival and regeneration in normal, predenervated, and Marcaine-treated free muscle grafts in the rat. *Exp. Neurol.*, 52:421-432.

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1976 Gutmann, E. and B.M. Carlson. Innervation of free muscle grafts in the rat in the absence of mechanical trauma to surrounding muscles or nerves. *Life Sciences*, 19:649-656.

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1981 Max, S.R., S. Mufti and B.M. Carlson. Cytosolic androgen receptor in regenerating rat levator ani muscle. *Biochem. J.*, 200:77-82.

1981 Carlson, B.M. The development of facial muscles and nerves in relation to the Mobius syndrome. *Otolaryngol. Head Neck Surg.*, 89:903-906.

1981 Carlson, B.M., P. Hník, S. Tucek, R. Vejsada, D.M. Bader and J.A. Faulkner. Comparison between grafts with intact nerves and standard free grafts of the rat extensor digitorum longus muscle. *Physiol. Bohemoslovaca*, 30:505-513.

1982 Carlson, B.M. The regeneration of axolotl limbs covered by frog skin. *Devel. Biol.*, 90:435-440.

1982 Carlson, B.M. Morphogenesis of the regenerating amphibian limb (in Russian). *Ontogenet.*, 13:339-359.

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1983 Carlson, B.M. and J.A. Faulkner. The regeneration of skeletal muscle fibers following injury. *Med. and Sci. in Sports and Exercise*, 15:187-198.

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1985 Faulkner, J.A., and B.M. Carlson. Contractile properties of standard and nerve-intact muscle grafts in the rat. *Muscle and Nerve*, 8:413-418.

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1985 Carlson, B.M., and E.A. Rainin Rat extraocular muscle regeneration: Repair of local anesthetic-induced damage. *Arch. Ophthalmol.*, 103: 1373-1377.

1986 Carlson, B.M., B.K. Simandl, K.M. Stocker, T.G. Connelly and John F. Fallon 1986. A method for combined gross skeletal staining and Feulgen staining of embryonic chick tissues. *Stain Technol.*, 61:27-31.

1986 Brodsky, V. Ya., B.M. Carlson and A.M. Arefieva Polyploidization of cardiac myocytes as a programmed event of ontogenesis (in Russian). *Ontogeny*, 17(2):138-145.

1986 Faulkner, J.A., and B.M. Carlson. Skeletal muscle regeneration: A historical perspective. *Fed. Proc.*, 45:1454-1455.

1986 Schwartz, J., J. Wiesen, B. Carlson, L. Yamasaki, M. Moore and M. Womble. Increased phenylalanine incorporation in regenerating skeletal muscle grafts. *Canad. J. Physiol. Pharmacol.*, 64:199-205.

1986 Carlson, B.M. Regeneration of entire skeletal muscles. *Fed. Proc.*, 45:1456-1480.

1986 Mrázková, O., M. Grim and B.M. Carlson Enzymatic heterogeneity of the capillary bed of rat skeletal muscles. *Am. J. Anat.*, 177:141-148.

1986 Grim, M., O. Mrázková and B.M. Carlson Enzymatic differentiation of arterial and venous segments of the capillary level during the development of free muscle grafts in the rat. *Am. J. Anat.*, 177:149-159.

1987 Burton, H.W., B.M. Carlson and J.A. Faulkner Microcirculatory adaptation to skeletal muscle transplantation. *Ann. Rev. Physiol.*, 49:439-452.

1987 Griffin, K.J.P., D.M. Fekete and B.M. Carlson A monoclonal antibody stains myogenic cells in regenerating newt muscle. *Development*, 101:267-278.

1987 Phillips, G.D., D. Lu, V.I. Mitashov and B.M. Carlson Survival of myogenic cells in freely grafted rat rectus femoris and extensor digitorum longus muscles. *Am. J. Anat.*, 180:365-372.

1988 Stocker, K.M. and Carlson, B.M. Preservation of the ability of dissociated quail wing-bud mesoderm to elicit a position-related differentiative response. *Amer. J. Anat.*, 182:84-95.

1988 Carlson, Bruce M. A test of positional properties of avian wing-bud mesoderm. *Am. J. Anat.*, 182:96-105.

1988 Operpriller, J.O., J.C. Operpriller, A.M. Arefyeva, V.I. Mitashov and B.M. Carlson Nuclear characteristics of cardiac myocytes following the proliferative response to mincing of the myocardium of the adult newt. *Cell and Tiss. Res.*, 253:619-624.

1988 Carlson, B.M., and J.A. Faulkner. Reinnervation of long-term denervated rat muscle freely grafted into an innervated limb. *Exp. Neurol.*, 102, 50-56.

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1988 Brodsky, V. Ya, Carlson, B.M., Arefieva, A.M. and Vacilieva, I.A. Polyploidization of transplanted cardiac myocytes. *Cell Different.*, 25, 177-184.

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1989 Ökland, S., T.E. Komorowski, and B.M. Carlson. Ultrastructure of mepivacaine-induced damage and regeneration in rat extraocular muscle. *Invest. Ophthalmol. & Vis. Sci.*, 30:1643-1651.

1989 Carlson, B.M. and Faulkner, J.A. Muscle transplantation between young and old rats: Age of host determines functional recovery. *Am. J. Physiol.*, 256 (Cell Physiol. 25):C1262-1266.

1990 Stocker, K. and B.M. Carlson Hensen's node possesses ZPA activity in the avian embryo. *Roux' Arch.*, 198:371-381.

1990 Komorowski, T., Shepard, B., Ökland, S. and Carlson, B.M. An electron microscopic study of local anesthetic-induced skeletal muscle fiber degeneration and regeneration in the monkey. *J. Orthoped. Res.*, 8:495-503.

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1990 Brodsky, V. Ya., Carlson, B. and Arefieva, A.M. Similarities and differences of growth of the heart in situ and in transplants. (In Russian). *Ontogenesis*, 21:89-95.

1990 Carlson, B.M. Limb muscle regeneration in peripheral nerve autografts-discussion. *Plastic Reconstr. Surg.*, 85:935-936.

1990 Grim, M., and B.M. Carlson. Alkaline phosphatase and dipeptidylpeptidase IV staining of tissue components of skeletal muscle - a comparative study. *J. Histochem. Cytochem.*, 38:1907-1912.

1991 Blaivas, M., and B.M. Carlson Muscle fiber branching - difference between grafts in old and young rats. *Mech. Aging & Devel.*, 60:43-53.

1991 Messina, L.M. and B.M. Carlson. Rapid and complete recovery of responsiveness to adenosine and norepinephrine by regenerating arterioles of the tibialis anterior of the hamster after *in situ* grafting. *Circ. Res.*, 68:1600-1609.

1991 Carlson, E.C., and B.M. Carlson. A method for preparing skeletal muscle fiber basal laminae. *Anat. Rec.*, 230:325-331.

1991 Goldman, D., B.M. Carlson and J. Staple. Induction of adult-type in AChR gene-expression in non-innervated regenerating muscles. *Neuron*, 7:649-658.

1991 Thouveny, Y.R., T.E. Komorowski and B.M. Carlson. Early innervation of skeletal muscle during tail regeneration in amphibians. *J. Exp. Zool.*, 260:354-370.

1992 Carlson, B.M., S. Emerick, T.E. Komorowski, E.A. Rainin and B.M. Shepard. Extraocular muscle regeneration in primates: Local anesthetic-induced lesions. *Ophthalmology*, 99:582-589.

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1992 Guelinckx, P.J., B.M. Carlson and J.A. Faulkner. Morphological characteristics of muscles grafted in rabbits with neurovascular repair. *J. Reconstruc. Microsurg.*, 8:481-483.

1992 Arsanto, J.-P., T.E. Komorowski, F. Dupin, X. Canbit, M. Diano, J. Geraudie, B.M. Carlson and Y. Thouveny. Peripheral nervous system formation during tail regeneration in urodele amphibians: Ultrastructural and immunohistochemical studies of the origin of the cells. *J. Exp. Zool.*, 264:273-292.

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AAOS - American Association of Orthopaedic Surgery
Am. J. Anat. - American Journal of Anatomy
Am. Rev. Physiol. - Annual Review of Physiology
Am. Zool. - American Zoologist
Anat. Rec. - Anatomical Record
Anesth. Analg. - Anesthesia and Analgesia
Arch. Ophthalmol. - Archives of Ophthalmology
Biochem. J. - Biochemical Journal
Devel. Biol. - Developmental Biology
Dev. Dyn. -
Doklady Akad. Nauk SSSR - Doklady Akademii Nauk SSSR
Exp. Neurol. - Experimental Neurology
Fed. Proc. - Federation Proceedings
Folia Morph. - Folia Morphologica
J. Embryol. Exp. Morph. - Journal of Embryology and Experimental Morphology
J. Exp. Zool. - Journal of Experimental Zoology
J. Gerontol. - Journal of Gerontology
J. Morph. - Journal of Morphology
J. Neuro. Sci. - Journal of Neurological Sciences
Med. and Sci. in Sports and Exercise - Medicine and Science in Sports and Medicine
Microcircul. Res. - Microcirculatory Research
Mol. Cell. Biol. Res. - Molecular Cell Biology Research
Neurosci. Lett. - Neuroscience Letters
Otolaryngol. Head Neck Surg. - Otolaryngology, Head and Neck Surgery
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Phys. Bohemoslov - Physiologica Bohemoslovaca
Plast. Reconstr. Surg. - Plastic and Reconstructive Surgery
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